

Adapted MQSA regulations

Effective April 28, 1999

21 CFR 900.12(c)(1)(iv)

(The report shall contain) Overall final assessment of findings, classified in one of the following categories:

(0)	"Assessment Incomplete"	Additional studies and/or comparisons needed
(1)	"Negative"	Nothing to comment upon
(2)	"Benign"	Also a negative assessment
(3)	"Probably Benign"	Finding(s) with a high probability of being benign
(4)	"Suspicious"	Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant
(5)	"Highly suggestive of malignancy"	Finding(s) with a high probability of being malignant

21 CFR 900.12(c)(1)(v)

In cases where no final assessment category can be assigned due to incomplete workup, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

21 CFR 900.112(c)(1)(vi)

Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.